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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/987,108	11/13/2001	Jens Knudsen	KNUDSEN=1A	6445
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1444 7590 04/07/2004

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/987,108

Applicant(s)

KNUDSEN ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 46-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-45 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9 and 10.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This office action is in response to the supplemental election, received 12/31/03, in which applicant made the following elections, all with traverse:

- group II, claims 26-45 and 67
- SEQ ID NO:1 from claims 4 and 34
- Lys-50 from claims 12 and 42
- Acrylodan from claims 30 and 32.

Applicant contends that the inventions are related if they are not independent. The examiner has pointed out the different functions of the different inventions in the restriction requirement.

Applicant has asked for clarification as to whether the SEQ ID NO selection is a restriction requirement or an election of species. This is an election of species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-25 and 46-66 are withdrawn as being drawn to non-elected inventions.

Claims 26-45 and 67 are pending and will be examined to the extent that they read on SEQ ID NO:1, Lys-50, and acrylodan.

Information Disclosure Statement

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The information disclosure statements filed 4/2/02 (Paper No:9) and 10/3/02 (Paper No: 10) are acknowledged. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26- 45 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a construct consisting of the bovine acyl coenzyme A binding protein (ACBP) and the native amino acid being replaced by a cysteine residue consisting of Met-24 or Ala-53 fluorescently labeled with 6-bromoacetyl-2-dimethylaminonaphthalene (Badan) does not reasonably provide enablement for a construct for binding a hydrophobic Coenzyme A ester comprising a heterologous peptide capable of binding at least one species of hydrophobic Coenzyme A ester and a signal moiety. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art

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- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a construct for binding hydrophobic Coenzyme A ester comprising a heterologous peptide and a signal moiety. The heterologous peptide comprises the bovine acyl coenzyme A binding protein (ACBP) and the native amino acid being replaced by a cysteine residue selected from the group consisting of Met-24, Leu-25, Ala-53, Asp-21, Lys-50, Lys-54, Lys-18, pro-19, Ala-9, Tyr-31, Lys-32, Tyr-28, Tyr-73, Val-12, Lys-13, Leu-15 or Ile-27.

The breadth of the claims is excessive with regard to claiming a construct selected from the above group. Applicant has only provided guidance for the use of the bovine acyl coenzyme A binding protein (ACBP) and the native amino acid being replaced by a cysteine residue consisting of Met-24 or Ala-53 for binding hydrophobic Coenzyme A ester, see page 44, example 1, lines 13-29 of the instant specification. Applicant has provided no guidance of any other cysteine residue selected from the group consisting of Leu-25, Asp-21, Lys-50, Lys-54, Lys-18, pro-19, Ala-9, Tyr-31, Lys-32, Tyr-28, Tyr-73, Val-12, Lys-13, Leu-15 or Ile-27 being used for binding hydrophobic Coenzyme A ester. It would not be predictable to the artisan which residues comprising the bovine acyl coenzyme A binding protein (ACBP) and the native amino acid being replaced by a cysteine residue selected from the group consisting of Leu-25, Asp-21, Lys-50, Lys-54, Lys-18, pro-19, Ala-9, Tyr-31,

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Lys-32, Tyr-28, Tyr-73, Val-12, Lys-13, Leu-15 or Ile-27 being used for binding hydrophobic Coenzyme A ester would work in the present invention.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Claims 33, 34, and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common

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characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

These are genus claims. Applicant is claiming a construct comprising a bovine acyl coenzyme A binding protein (ACBP) , a variant or functional equivalent thereof for binding hydrophobic Coenzyme A ester. There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, i.e., SEQ ID NO:1. The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims encompass numerous species that are not further described. There is substantial variability among species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus which comprises the genus of constructs comprising a bovine acyl coenzyme A binding protein (ACBP) , a variant or functional equivalent thereof for binding hydrophobic Coenzyme A ester.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Klienfeld (USPN 5,470,714).

The claimed invention is drawn to a construct for binding hydrophobic Coenzyme A ester

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comprising a heterologous peptide capable of binding at least one species of hydrophobic Coenzyme A ester, and a signal moiety.

Klienfeld teaches a method for determining hydrophobic analytes, such as free hydrophobic analytes, e.g., free fatty acids, with a reagent comprising a fluorescently modified specific-binding protein for the hydrophobic analyte, detecting a fluorescence difference between the fluorescently modified specific-binding protein in the bound and unbound conditions, and relating said fluorescence difference to the amount of analyte in the solution disclosed, see abstract and column 16, claim 1. Klienfeld discloses the fluorescently modified specific-binding protein was labeled with Acrylodan, see column 6, line 66.

Therefore, the reference is deemed to anticipate the instant claims above.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER